

REMARKS

Applicant would like to thank the Examiner for his time during the teleconference of May 22, 2003 with Applicant's attorney, Johnney Han. During the teleconference, cited references (including WO 01/12104) were discussed in view of the claims as were possible amendments to the claims.

Claims 1-57 were pending in the present application. By virtue of this response, paragraphs [0013] and [0040] of the specification and claims 1 and 23 have been amended. Accordingly, claims 1-57 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any subject matter of the claims as previously presented.

Rejections Under 35 U.S.C. § 112, second paragraph

The Office has rejected claim 23 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In support of the rejection of claim 23, the Office Action (Paper No. 11) states the following on page 2:

Referring to this claim, this claim includes the trademark "Kraton". The proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. This trademark does not define a specific structure for the membrane material. The trademark defines a particular product and this can change depending on the manufacturers desires. Accordingly, Kraton is indefinite.

In response, claim 23 has been amended to remove the feature of "Kraton", thus rendering the rejection moot. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 102(b)

A. The Office has rejected claims 1; 2, 4, 6, 7, 9, 11, 13-15, 21-23, 31-33, 35 and 36 as allegedly being anticipated by Gianturco (5,334,210).

In support of the rejection of claims 1, 2, 4, 6, 7, 9, 11, 13-15, 21-23, 31-33, 35 and 36, the Office Action (Paper No. 11) states the following on page 3:

Gianturco teaches an embolizing device for insertion into an aneurysm including at least one self-expanding coil member configured to pass through at least one orifice of a membrane and be sealed within the membrane. Gianturco teaches the membrane comprising a distensible bag formed of a diamond shape when expanded and including at least one orifice for allowing connection with a catheter 12 and the insertion of the self-expanding member 18. the self-expanding member consists of a wire with a hooked end. As the wire is pushed (stimulated) through the catheter the said end is compressed and when the wire exits the catheter it expands and forms the hook end using it's "memory" characteristics for filling the diamond shaped membrane. The bag is connected to the delivering device using a mechanical joint which is disconnected once the bag is properly in place and expanded.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). (MPEP §2131.)

Independent claim 1 recites at least one "self-expanding member". Support is found throughout the specification. As described, the self-expanding member reconfigures from a first configuration into a larger, expanded configuration causing the membrane to expand. (Specification, [0013] & Figs. 2A to 3B.) On the other hand, Gianturco shows and describes a device in which "[f]lexible elongated member 18, or filler member 18, is positioned in internal cavity 20 ... by pushing distally on the handle." (Gianturco, 4: 30-33.) As further described, "[w]hen the flexible elongated material is convoluted and positioned in the folded material occlusion bag, the bag assumes expanded shape 31." (Gianturco, 4: 37-40; Figs. 2 & 4.)

The device of Gianturco is thus expanded by forcing a filler member into an occlusion bag which forces the bag to expand. There is simply no disclosure in Gianturco of a "self-expanding member"; rather, the coil (member), is described as "an appropriate length of 0.025" diameter stainless steel coil". (Gianturco, 3: 39-40.) Therefore, Gianturco cannot anticipate claim 1 and dependent claims 2, 4, 6, 7, 9, 11, 13-15, 21-23, 31-33, 35 and 36, which depend ultimately from claim 1, are patentable for at least the same reasons.

Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

B. The Office has rejected claims 1-4, 13-23, 31-33, and 35-37 as allegedly being anticipated by Jeffree (WO 99/03404).

In support of the rejection of claims 1-4, 13-23, 31-33, and 35-37, the Office Action (Paper No. 11) states the following on page 4:

Jeffree teaches an embolizing device for insertion into an aneurysm including at least one self-expanding member configured to pass through at least one orifice of a membrane and be sealed within the membrane. Jeffree teaches the membrane comprising a distensible bag formed of Lycra (which is a tradename for, which is comprised of polyurethane). The bag includes at least one orifice for allowing connection with a delivery device 14 and the insertion of the self-expanding member 18. The self-expanding member consists of a wire having memory characteristics. As the wire is pushed (stimulated) through the delivery device the wire exits the catheter and enters at least one orifice in the bag where it expands and fills the distensible bag. The bag is further taught as including a plurality of orifices allowing blood to pass through the bag walls. The bag is connected to the delivering device using a mechanical joint which is connected once the bag is properly in place and expanded. The joint is disconnected by the application of an electrical energy after the bag is located and expanded as desired.

As described above, independent claim 1 recites at least one "self-expanding member", which is due to shape memory characteristics. The self-expanding member reconfigures from a first configuration into a larger, expanded configuration causing the membrane to expand. (Specification, [0013] & Figs. 2A to 3B.) On the other hand, Jeffree shows and describes a device in which "[bag 31] is inserted into the aneurysm 20 ... while GD coils 18 (or other materials) are inserted into it, thus expanding it against the walls of the aneurysm." (Jeffree, p. 6, ¶ 3.) As further described, "GD coils 18 attached to respective pusher wires 11 are then introduced sequentially along catheter 14 and inserted in the bag 31 The bag then expands to conform to the interior of the aneurysm as shown in Fig. 3." (Jeffree, p. 7, ¶ 2-3.)

Thus, the device of Jeffree, much like Gianturco, is thus expanded by forcing GD coils into a bag which forces the bag to expand. As in Gianturco, there is simply no disclosure in Jeffree of a "self-expanding member"; rather, the GD coils are described as being "simply a soft

platinum coil." (Jeffree, p. 2, ¶ 3.) The Office Action at p. 4, ¶ 2 contends that "[t]he self-expanding member consists of a wire having memory characteristics"; however, Jeffree fails to disclose such a wire with memory characteristics. Therefore, Jeffree cannot anticipate claim 1 and dependent claims 2-4, 13-23, 31-33, and 35-37, which depend ultimately from claim 1, are patentable for at least the same reasons.

Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

Rejections Under 35 U.S.C. § 103(a)

The Office has rejected claim 5 as allegedly being unpatentable over Jeffree as applied to the claims above, and further in view of Mazzocchi (WO 97/26939).

In support of the rejection of claim 5, the Office Action (Paper No. 11) states the following on page 5:

Jeffree discloses the invention substantially as claimed. See above for specific structural details. Briefly, Jeffree teaches an embolizing device for insertion in aneurysm including a self-expanding member within a distensible membrane. Jeffree teaches the self-expanding member including a metal wire having "memory" characteristics. However, Jeffree does not teach the wire comprising a Nickel Titanium alloy.

Mazzocchi teaches a occlusion device for an aneurysm formed of a self-expanding metal mesh comprising a Nickel Titanium alloy.

It would have been obvious to a person having ordinary skill in the art of occluders at the time of applicant's invention to construct the wire of Jeffree as including NiTi. Providing such wire would allow the proper "memory" characteristics. Further, the composition would allow the wire to not interact with the chemical make up of the human body and thus not cause adverse effects.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success.

Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143.

Dependent claim 5 depends from claim 1 and is therefore patentable for at least the same reasons as claim 1. Mazzocchi, either alone or in combination with any other reference, necessarily fails to cure the defects of Jeffree. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

Allowable Subject Matter

The Office has indicated that claims 38-57 are allowable over the art of record. The Office has also indicated that claims 8, 10, 12, 24-30 and 34 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant acknowledges the allowable subject matter with thanks. However, Applicant contends that in light of the remarks above, all pending claims are allowable and respectfully requests allowance therefor.

CONCLUSION

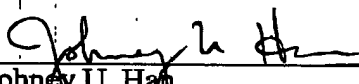
Applicant has, by way of the amendments and remarks presented herein, made a sincere effort to overcome rejections and address all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 509192000100. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: May 23, 2003

By:


John U. Ham
Registration No. 45,565

Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018
Telephone: (650) 813-5786
Facsimile: (650) 494-0792